



## **National Association of Boards of Pharmacy**

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nabp

July 20, 2005

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Ln, Room 1061  
Rockville, MD 20852

Re: Useful Written Consumer Medication Information: Requests for Public Comment [Docket No. 2005D-0169]

The purpose of this correspondence is to provide comments and suggestions concerning the “Useful Written Consumer Medication Information (CMI)” draft guidance pursuant to the May 26, 2005 Federal Register notice by the United States Food and Drug Administration (FDA). The National Association of Boards of Pharmacy® (NABP®), founded in 1904, represents all of the pharmacy regulatory and licensing jurisdictions in the US, Guam, Puerto Rico, the Virgin Islands, eight provinces of Canada, two states in Australia, New Zealand, and South Africa. NABP’s purpose is to serve as the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

NABP has been actively involved in the development of CMI since 1996 when it was appointed a member of the Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, which developed the report entitled “Action Plan for the Provision of Useful Prescription Medicine Information.” As the FDA draft guidance states, NABP also developed both a pilot study and a national study (Svarstad, BL and JK Mount, *Evaluation of Written Prescription Information Provided in Community Pharmacies*, December 2001) to assess the extent to which the year 2000 goals specified in the law (ie, 75% of people receiving new prescriptions would receive useful written patient information along with them) had been achieved. NABP’s active involvement in the development of CMI, that meets the requirement of “useful to consumers,” continued with its participation in the National Council on Patient Information and Education’s (NCPPIE) stakeholder’s project, which is still underway.

In 2004, the NABP membership passed Resolution 100-6-04, Medication Identification:

Whereas, the ultimate goal of all pharmacy practice is to assure positive patient outcomes through the optimization of the correct and most appropriate medication therapy; and  
Whereas, the technology presently exists and is being used in several states whereby a pictorial representation or written description of a drug can be placed on the prescription

label and/or printed patient information; and

Whereas, other states have mandated that a pictorial representation or written description of a drug be placed on most prescription labels; and

Whereas, the use of a pictorial representation or written description of a drug on a prescription label and/or printed patient information will enhance the opportunity for pharmacists and patients to identify and prevent medication errors before the errors cause harm;

THEREFORE BE IT RESOLVED that NABP work with interested stakeholders, including manufacturers who develop the digital images and/or written descriptions, to develop, promote, and encourage that all prescription labels contain a pictorial representation and/or written description of the medication.

As result of Resolution 100-6-04 (Medication Identification), NABP has sought assistance from organizations like the American Society of Automation in Pharmacy to identify companies that offer digital imaging and associated technologies. NABP has also urged the Pharmaceutical Research and Manufacturers of America to encourage manufacturers to provide digital images and/or written descriptions to digital imaging companies in order to ultimately promote and encourage the widespread use of pictorial and written descriptions of the medication on prescription labels and printed information (or CMI). Some states, such as California, Georgia, Oregon, and Wyoming currently mandate that the prescription label of dispensed medication contain a written description of the product.

Therefore, NABP encourages the inclusion of pictorials and/or written descriptions (physical description of the medication, including its color, shape, and any identification code that appears on the tablet or capsule) of medications as a specific recommendation of Criterion 1 (Drug Name, Indications for Use, and How to Monitor for Improvement) in the final "Guidance on Useful Written Consumer Medication Information." NABP believes that the inclusion of such information would not only aid in reducing medication errors, but may also assist the patient in identifying products that could be potentially counterfeit or substandard.

If I can provide any additional information, please contact me. Thank you for the opportunity to address this important issue.

Sincerely,

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Professional Affairs Director

EZA/cj

Division of Dockets Management (HFA-305)

July 20, 2005

Page 3

cc: NABP Executive Committee  
Carmen A. Catizone, Executive Director/Secretary